Amendments to the Specification:

Please replace the paragraph starting on page 1, line 41 of the specification with the following amended paragraph:

This application claims the benefit of U.S. Provisional Patent Applications Numbers 60/471,520 filed May 15, 2003 ~~(attorney docket no. 11300-0003-888~~ and 60/420,555 filed October 23, 2002 ~~(attorney docket no. PDC 05)~~. The entire disclosures of each of the aforesaid patent applications [[is]] are hereby incorporated herein by this specific reference thereto.

Please replace the paragraph starting on page 10, line 25 of the specification with the following amended paragraph:

Figure 6 is ~~a side view of an embodiment of an aneurysm treatment implant in accordance with the present invention shaped like a bowl with a flat bottom, having a central projection protruding from the top of the bowl~~ a longitudinal cross section of a saccular aneurysm and corresponding artery segment with an embodiment of an aneurysm treatment implant of the present invention in an expanded state implanted in a saccular aneurysm;

Please replace the paragraph starting on page 10, line 28 of the specification with the following amended paragraph:

Figure 7 is ~~a side view of the embodiment illustrated in Figure 6~~ a longitudinal cross section of a saccular aneurysm and corresponding artery segment with an embodiment of an aneurysm treatment implant of the present invention, having reinforcing ribs, in an expanded state implanted in a saccular aneurysm;

Please replace the paragraph starting on page 11, line 3 of the specification with the following amended paragraph:

Figure 9 is ~~a longitudinal cross section of a saccular aneurysm and corresponding artery segment with embodiments of the present invention in an expanded state implanted in a saccular aneurysm~~ a longitudinal cross section of an artery similar to that illustrated in Figure 6 further illustrating the addition of a sheath in the lumen of the artery, covering the neck of the aneurysm;

Please replace the paragraph starting on page 11, line 6 of the specification with the following amended paragraph:

Figure 10 is ~~an embodiment covering the neck of the aneurysm~~ a side view of an embodiment of an aneurysm treatment implant in accordance with the present invention shaped like a bowl with a flat bottom, having a central projection upstanding in the bowl;

Please replace the paragraph starting on page 11, line 9 of the specification with the following amended paragraph:

Figure 11 is ~~a longitudinal cross section of an artery similar to that illustrated in Figure 9 further illustrating an embodiment of the present invention with ribs~~ a top view of the embodiment illustrated in Figure 10;

Please replace the paragraph starting on page 14, line 8 of the specification with the following amended paragraph:

Referring again to Figure[[s]] 6 the illustrated implant can be formed of a composite hydrophilically coated hydrophobic foam, as described hereinbelow or of other suitable material as is described herein, and is shaped like an inverted umbrella or a bowl with a central projection 12 upstanding in the bowl. Implant 10 has a flattened area 14 an outer, generally convex surface and has an inner generally concave surface 18. Extending downwardly from top surface, around the perimeter of top surface are side walls that curve outwardly from flattened area 14. If desired, reinforcing ribs (not shown) can be provided on inner surface to increase the overall resiliency of the bowl enhancing its ability to expand to shape *in situ*.

Please replace the paragraph starting on page 14, line 19 of the specification with the following amended paragraph:

In one embodiment of the present invention, the width or thickness of projection ~~12~~ 24 is sufficient to provide structural support to the implant and enable implant ~~10~~ to be effectively manipulated by gripping the distal tip of projection ~~12~~ 24. To this end, projection ~~12~~ 24 may have a thickness of approximately 10 to 40 percent of the diameter defined by side walls. However, in application the projection may be thicker or narrower to serve desired purposes, such as support or collapsability for insertion into the catheter. In the embodiment shown, the outer surface 12 of implant ~~10~~ is relatively smooth and designed to contact the majority of the inner wall of the aneurysm.

Please replace the paragraph starting on page 15, line 8 of the specification with the following amended paragraph:

As shown in Figure[[s]] 6, implant 10 is generally circular as seen in plan. However, implant 10 may have any desired shape in plan, although symmetrical shapes such as elliptical or oval are preferred. Nevertheless, polygonal shapes such as hexagonal, octagonal or dodecagonal can be employed, if desired. Furthermore, it will be appreciated that the cross sectional shape in plan need not be geometrically regular. For example, employing a reticulated biodurable elastomeric matrix, a polymeric foam, or a comparably cleavable material, as the primary structural material of the implant, the implant can readily be trimmed to shape by the surgeon, before implantation, if desired, e.g. to fit an irregular structure within the aneurysm, possibly by making a concave, bite-shaped cutout in side walls ~~20~~.

Please replace the paragraph starting on page 16, line 2 of the specification with the following amended paragraph:

In the embodiment illustrated in Figure 13 side walls 40 continue the curve of the rounded bottom 44, such that the side walls 40 have a convex shape. Convex walls 40 can aid in allowing blood flow within the aneurysm 7 while providing a means to accommodate pressure produced within the aneurysm. For example, instead of the pressure within the aneurysm 7 being directed toward the neck of the aneurysm, the convex shape of side walls 40 approximates the shape of the inner walls of the aneurysm in the vicinity of the neck and helps relieve pressure on those walls. Furthermore, pressure directed within bowl 48 will be diverted toward the inner surface 47 of walls ~~46~~ <u>40</u>.

Please replace the paragraph starting on page 16, line 12 of the specification with the following amended paragraph:

Each region of implant 310 serves a particular purpose. Bowl 46 is inserted into an aneurysm and provides support to the walls of the aneurysm. Column 42 provides support to the neck of the aneurysm. Base 36 can remain outside of the aneurysm, in the lumen of the affected artery and serves to keep implant ~~210~~ 310 in place. Further, if desired in some variants of implant ~~210~~ 310, base 36 can be placed against the antrum of the aneurysm and the surrounding arterial wall and serve to seal off the aneurysm.

Please replace the paragraph starting on page 17, line 19 of the specification with the following amended paragraph:

Referring to Figure 9, implant 10 may be seen situated in a saccular aneurysm 7. In this example, the surgeon has implanted a portion 12 of implant 10 against the artery walls most distal from the neck of the aneurysm 7, and another portion 22 of implant 10 in the region of neck, and extending out of the antrum into the artery below. When properly located *in situ*, pursuant to the teachings of this invention, implant[[s]] 10 can immediately protect the aneurysm walls from the pulsating pressure of the blood within the aneurysm which might otherwise exploit a particular weakness in the already distended aneurysm wall, resulting in catastrophic failure of the aneurysm. While the walls are so protected, the presence of implant[[s]] 10, optionally including one or more pharmacologic agents borne on the or each implant, stimulates fibroblast proliferation, growth of scar tissue around the implants and eventual immobilization of the aneurysm.

Please replace the paragraph starting on page 18, line 13 of the specification with the following amended paragraph:

~~Alternatively, as is illustrated in Figure 10,~~ The implants may be used ~~described~~ in combination with a semicircular sectioned sheath, such as supplied by Boston Scientific Corporation that is applied to the wall of the artery such that the neck of the aneurysm is substantially centered under the middle of the sheath and blood flow to the aneurysm is cut off. Alternatively, sheath can be perforated to allow blood flow into the aneurysm.

Please replace the paragraph starting on page 19, line 6 of the specification with the following amended paragraph:

Implants of Figs. 10 and 12 are designed such that their outer surfaces contact the inner walls of the aneurysm 7. The center projections 24, 224 can provide support and distribution of the forces exerted by the aneurysm walls. Additionally, projection 24, 224 can be used by the surgeon to further position such implant(s) ~~120, 210~~ once inserted and released from the catheter.

Please replace the paragraph starting on page 20, line 14 of the specification with the following amended paragraph:

Figure 19 illustrates an implant 250 wherein the top 256 and bottom 252 portions are substantially solid and the side walls comprises thin strips ~~260~~. As is illustrated in Figures 20 and 21 which illustrates two embodiments of implant 250, the cross section of implant 250 can be hollow ~~262~~, where the side wall strips ~~260~~ 262 are just around the perimeter of implant 250 (Fig. 20). Alternatively, as is illustrated in Fig. 21, the cross sections~~, 362,~~ as viewed along lines 20-20 can be made up of strips 362 that take up substantially the entire cross section of implant 250.

Please replace the paragraph starting on page 21, line 12 of the specification with the following amended paragraph:

While shown as largely smooth, the outer peripheries of implants ~~922~~ can have more complex shapes for desired purposes, for example, corrugated. It is contemplated that a tapered or bullet-shaped outer profile may facilitate delivery, especially of later implants arriving after a proportion of the intended group of implants has already been delivered to the target site and may offer resistance to the accommodation of newly arriving implants. For this purpose the tapered or bullet end of the implant can be oriented distally in the introducer to facilitate reception of the implant into the aneurysm volume.

Please replace the paragraph starting on page 24, line 24 of the specification with the following amended paragraph:

In another embodiment, the implantable device or device system <u>can</u> cause[[s]] cellular ingrowth and proliferation throughout the site, throughout the site boundary, or through some of the exposed surfaces, thereby sealing the site. Over time, this induced fibrovascular entity resulting from tissue ingrowth can cause the implantable device to be incorporated into the conduit. Tissue ingrowth can lead to very effective resistance to migration of the implantable device over time. It may also prevent recanalization of the aneurysm or other target site. In another embodiment, the tissue ingrowth is scar tissue which can be long-lasting, innocuous and/or mechanically stable. In another embodiment, over the course of time, for example for 2 weeks to 3 months to 1 year, implanted reticulated elastomeric matrix <u>may</u> become[[s]] completely filled and/or encapsulated by tissue, fibrous tissue, scar tissue or the like.

Please replace the paragraph starting on page 24, line 24 of the specification with the following amended paragraph:

In another embodiment, for aneurysm treatment, a reticulated elastomeric matrix [[is]]<u>may be</u> placed between a target site wall and a graft element that is inserted to treat the aneurysm. Typically, when a graft element is used alone to treat an aneurysm, it becomes partially surrounded by ingrown tissue, which may provide a site where an aneurysm can re-form or a secondary aneurysm can form. In some cases, even after the graft is implanted to treat the aneurysm, undesirable occlusions, fluid entrapments or fluid pools may occur, thereby reducing the efficacy of the implanted graft. By employing the inventive reticulated elastomeric matrix, as described herein, it is thought, without being bound by any particular theory, that such occlusions, fluid entrapments or fluid pools can be avoided and that the treated site may become completely ingrown with tissue, including fibrous tissue and/or endothelial tissues, secured against blood leakage or risk of hemorrhage, and effectively shrunk. In one embodiment, the implantable device may be immobilized by fibrous encapsulation and the site may even become sealed, more or less permanently.

Please replace the paragraph starting on page 26, line 4 of the specification with the following amended paragraph:

In one embodiment, a patient [[is]]<u>may be</u> treated using an implantable device or a device system that does not, in and of itself, entirely fill the target cavity or other site in which the device system resides, in reference to the volume defined within the entrance to the site. In one embodiment, the implantable device or device system does not entirely fill the target cavity or other site in which the implant system resides even after the elastomeric matrix pores are

occupied by biological fluids or tissue. In another embodiment, the fully expanded in situ volume of the implantable device or device system is at least 5 even 10 % less than the volume of the site. In another embodiment, the fully expanded in situ volume of the implantable device or device system is at least 15% less than the volume of the site. In another embodiment, the fully expanded in situ volume of the implantable device or device system is at least 30% less than the volume of the site.

Please replace the paragraph starting on page 36, line 13 of the specification with the following amended paragraph:

The isocyanate index, a quantity well known to those in the art, is the mole ratio of the number of isocyanate groups in a formulation available for reaction to the number of groups in the formulation that are able to react with those isocyanate groups, e.g., the reactive groups of diol(s), polyol component(s), chain extender(s) and water, when present. In one embodiment, the isocyanate index is from about 0.9 to about 1.1. In another embodiment, the isocyanate index is from about 0.9 to about 1.02. In another embodiment, the isocyanate index is from about 0.98 to about 1.02. In another embodiment, the isocyanate index is from about 0.9 to about 1.0. In another embodiment, the isocyanate index is from about 0.9 to about 0.98.~~[0029]~~ The elastomeric polyurethane may contain 10 to 70 % by weight of hard segment, preferably 15 to 35% by weight of hard segment and may contain 30 to 85 % by weight of soft segment, preferably 50 to 80 % by weight of soft segment.

Please replace the paragraph starting on page 42, line 15 of the specification with the following amended paragraph:

Tensile tests are conducted on samples that are cut both parallel and perpendicular to the direction of foam rise. The dog-bone shaped tensile specimens are cut from blocks of foam each about 12.5 mm thick, about 25.4 mm wide and about 140 mm long. Tensile properties (strength and elongation at break) are measured using an INSTRON Universal Testing Instrument Model 1122 with a cross-head speed of 500 mm/min (19.6 inches/minute). The average tensile strength, measured from two orthogonal directions with respect to foam rise, is 24.64[[+]]±2.35 psi. The elongation to break is approximately 215[[+]]±12%.

Please replace the paragraph starting on page 42, line 24 of the specification with the following amended paragraph:

Compressive strengths of the foam are measured with specimens measuring 50 mm x 50 mm x 25 mm. The tests are conducted using an INSTRON Universal Testing Instrument Model 1122 with a cross-head speed of 10 mm/min (0.4 inches/min). The compressive strength at 50% is about [[12+]]1.2±0.3 psi. The compression set after subjecting the sample to 50% compression for 22 hours at 40 °C. and releasing the stress is 2%.

Please replace the paragraph starting on page 43, line 2 of the specification with the following amended paragraph:

Tear resistance strength of the foam is measured with specimens measuring approximately 152 mm x 25 mm x 12.7 mm. A 40 mm cut is made on one side of each specimen. The tear strength is measured using an INSTRON Universal Testing Instrument Model 1122 with a cross-head speed of 500 mm/min (19.6 inches/minute). The tear strength is determined to be about 2.9[[+]]±0.1lbs/inch. In the subsequent reticulation procedure, a block of

foam is placed into a pressure chamber, the doors of the chamber are closed and an airtight seal is maintained. The pressure is reduced to below 8 millitorr to remove substantially all of the air in the foam. A combustible ratio of hydrogen to oxygen gas is charged into the chamber for greater than 3 minutes. The gas in the chamber is then ignited by a spark plug. The ignition explodes the gasses within the foam cell structure. This explosion blows out many of the foam cell windows, thereby creating a reticulated elastomeric matrix structure.

Please replace the paragraph starting on page 43, line 28 of the specification with the following amended paragraph:

Post reticulation compressive strengths of the foam are measured with specimens measuring 50 mm x 50 mm x 25 mm. The tests are conducted using an INSTRON Universal Testing Instrument Model 1122 with a cross-head speed of 10 mm/min (0.4 inches/min). The compressive strength at 50% is about [[6.5]] <u>0.65</u> psi.